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(71) Applicant: TYCO GROUP S.A.R.L. [LU/LU]; 2nd floor, 6, avenue Emile Reuter, L–2420 Luxembourg (LU).

(72) Inventor: HUANG, Yeong, Hua; 2163 Palestra Drive 11, St. Louis, MO 63146 (US).

(74) Agent: SCHALCH, Rainer; E. Blum & Co., Vorderberg 11, CH–8044 Zürich (CH).

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(54) Title: LUBRICIOUS COATING

(57) Abstract

A lubricant coating for medical devices used to reduce the coefficient of friction of such devices upon exposure thereof to moisture.

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LUBRICIOUS COATING

Field of the Invention

The present invention relates to a lubricant coating for medical devices, and more particularly, to a hydrophilic polymeric coating composition which aids medical devices to become slippery when wetted. The composition of the present invention may be employed as a lubricant coating to reduce the coefficient of friction of catheters, arterial venous shunts, gastroenteric feed tubes, endotracheal tubes and other medical implants or polymeric substrates. Methods are also provided for the manufacture of the subject lubricant coating and for the application of the same to surfaces of medical devices.

Background of the Invention

Known lubricant coatings applied to surfaces of medical devices include coatings of polyvinylpyrrolidone, polyethylene oxide, hyaluronic acid and its salts, polyacrylic acid and its derivatives, polyurethane, acrylic polyester, fluorocarbons, silicone, and combinations of these substances. For example, Micklus et al., U.S. Patent Nos. 4,100,309 and 4,119,094 relate to a hydrophilic coating of polyvinylpyrrolidone-polyurethane interpolymer formed using polyisocyanate. Ratner et al., U.S. Patent No. 3,939,049 relates to a method of grafting hydrogels for lubrication to polymeric substrates using radiation. Hungton et al., U.S. Patent No. 3,975,350 relates to hydrophilic polyurethane polymers for use as lubricants. Storey et al., U.S. Patent No. 3,987,497, relates to a tendon prothesis having a lubricant hydrogel coating. Many known lubricious coatings are prone to various disadvantages when used in the medical field. Disadvantages of such known lubricants may include insufficiently low coefficient of friction, lack of

permanence and hydrophilicity such as characteristic of silicone- or fluorocarbon-based coatings, slipperiness when dry as well as wet thus making handling difficult, utilization of hazardous solvents in the manufacture of the same and utilization of unstable reactive materials in the manufacture of the same. Lubricants produced for medical use from unstable reactive material often require the coating solution to be prepared daily or more frequently to be useful and thereby increases waste and expense. Lubricants produced for medical use involving hazardous solvents are undesirable due to patient toxicity concerns and OSHA considerations.

In order to solve these and other potential disadvantages of known lubricants such as those of the above-cited patents incorporated herein by reference, a lubricant coating is needed which when wetted has sufficient lubricity to be useful in the medical device field such as for medical implants. The lubricant coating must be capable of adhering to a wide variety of substrates and resist wet abrasion. It would also be desirable to have such a lubricant coating prepared from chemically stable and biocompatible solvents.

Summary of the Invention

The present invention provides a lubricant coating composition comprising a hydrophilic polymer comprising polyvinylpyrrolidone, polyoxyethylene-based isocyanate-terminated prepolymer, ethyl lactate and toluene. The present invention also provides a method of making the subject lubricant coating which adheres to a wide variety of substrates and resists wet abrasion. The subject lubricant coating is chemically stable and is biocompable as described in greater detail below.

A method for using the subject lubricant coating composition to coat medical devices is provided herein which

involves cleaning or washing, drying, dip coating or applying of the lubricant, air drying or removal of excess lubricant, optionally baking and packaging a medical device either before or after sterilization thereof.

The present invention also provides a medical device whereby at least a portion thereof is coated with the subject lubricant coating composition which is characterized as being able to achieve a wetted lubricity with a reduction of friction of more than fifty (50) percent.

Detailed Description of the Invention

The composition of the present invention has been found particularly useful as a lubricant coating in lowering the coefficient of friction of medical devices such as indwelling thoracic catheters and other medical devices. The subject coating is manufactured from a blend of one or more C1-12 alkylbenzenes such as for example, toluene, xylene, or styrene but preferably toluene to increase stability, a C1-12 alkylester of a carboxylic acid such as for example, ethyl lactate, methylbenzoate, or propolyacrylate wherein ethyl lactate is preferred to increase stability, a polymer such as for example polyvinylpyrrolidone, polyvinyl alcohol, polyacrylic acid or a derivative thereof, hyaluronic acid or a salt thereof or polyethylene oxide, but preferably polyvinylpyrrolidone to increase hydrophilicity and lubricity, and an isocyanate-terminated prepolymer such as for example polyoxyethylene-based isocyanate such as a toluene or isophorone diisocyanate-based prepolymer and preferably Hypol* PreMA G60 manufactured by Hampshire Corporation, Lexington, Massachusetts, to increase binding strength. For further examples of suitable polyisocyanates see Encyclopedia of Polymer Science and Technology, H. F. Mark, N. G. Gaylord and N. M. Bikeles (eds.) (1969) incorporated herein by reference.

The lubricant coating of the present invention is generally prepared by first obtaining a mixing vat in which to prepare the solution. The mixing vat should be dry and free of water and alcohol. The present lubricant coating composition is preferably blended at room temperature according to the following component ratios described as follows in weight percent; i.e., 1 to 4 weight percent but preferably 1.9 weight percent polyvinylpyrrolidone, 0.5 to 3 weight percent but preferably 1.1 weight percent of the polyoxyethylene-based isocyanate-terminated prepolymer, 15 to 25 weight percent but preferably 18 weight percent alkylester of a carboxylic acid and 60 to 80 weight percent but preferably 79 weight percent toluene. The solution is mixed thoroughly until the polyvinylpyrrolidone and the prepolymer are completely dissolved. The component blending requires approximately 20 to 40 minutes but most usually about 30 minutes. The resulting lubricant coating solution should appear crystal clear with light yellow color. Prior to coating medical devices with the present lubricant coating solution, the particular medical device, such as a catheter, should for best results be cleaned by first filling a container with 100% isopropanol. The medical device is then dip washed in the isopropanol for approximately 5 seconds and dried by forced air at approximately 50 to 90° C to remove surface residual isopropanol and debris. The device should at this point be completely isopropanol free. The medical device is then dip coated for about 2 to 15 seconds in the lubricant coating solution while it is still warm to hot from the forced air drying and slowly removed from the solution vat at a rate of about 1 to 4 centimeters per second. The catheter or other medical device is then air dried at room temperature and less than about 40 percent humidity but preferably between 20 to 30 percent humidity for about 2 to 30 seconds but preferably 3 to 5 seconds to allow any excess lubricant

coating solution to drain off. Optionally, excess lubricant may also be removed using absorbent towels. After air drying, the coated medical devices are baked in forced air ovens at approximately 70° C to 120° C preferably at 80° C for approximately 30 minutes to 3 hours but most preferably for one hour and then removed from the oven. The medical devices are preferably checked for adequate transparency and to ensure that no solvent smell is present.

In packaging the subject medical devices coated in accordance with the present invention, the devices should not be allowed to touch one another if the humidity is above about 60 percent. High humidity should likewise be avoided in that it could cause undesirable moisture absorption by the lubricant coating. To prevent or avoid contact between the coated medical devices, each device may be packed in either paper, polyethylene tubing or the like depending on the shape of the particular device. If necessary, due to high atmospheric humidity, a desiccant may likewise be necessary in the packaging.

The preferred method of making and using the lubricant coating of the present invention is described in even greater detail in the following examples which are provided for purposes of further illustration. The following examples as described are not intended to be construed as limiting the scope of the present invention.

Example 1:

A lubricious coating was prepared by blending at room temperature the following components in a mixing vat for approximately 30 minutes until fully dissolved to form a crystal clear solution with a light yellow color.

	wt%
Polyvinylpyrrolidone	2.0
Ethyl lactate	18.0
Toluene	77.8
Isocyanate-terminated prepolymer	1.2

Example 2:

Thoracic catheters made of polyvinyl chloride (PVC) were washed with isopropanol and dried at 80° C for 30 minutes. The catheters were dipped coated for 10 seconds while the catheters were still warm. After dipping, excessive coating was removed using paper towels. The catheters were then immediately baked at 80° C for 60 minutes. The resultant coating was transparent and colorless with good bonding. The coating was very lubricious when wet. The friction reduction was up to 60%.

B. Biocompatibility tests

The coated catheters were first tested for hemolysis and then tested for lubricity using 1) protein adsorption and 2) platelet adhesion. The results of these tests show no hemolysis and improved lubricity as noted by a reduction of protein adsorption and platelet adhesion by more than 90% as set forth below.

1. Hemolysis

Using protein electrophoresis, no hemoglobin was seen in the supernatant of the PVP-coated thoracic catheter, nor was any seen in the hemolysis-negative control sample. As a comparison, rabbit hemoglobin was seen in gels stained with rabbit hemoglobin and the hemolysis-positive control. The results imply that the hydrophilic coating showed no sign of causing hemolysis.

2. Lubricity

a) Protein (fibrinogen)adsorption

Table 1 summarizes protein adsorption on the subject coated catheter surfaces and that of the control samples.

Table 1

material	n	ng	ng/cm²"
control	4	1620±69	339.3±14.4
PVP-coated	4	87.6±27.1	18.3±5.7

": ID=0.4 cm, total surface area of 3.8 cm tubing =4.7cm²

Test results show the adsorption of fibrinogen onto the hydrophilic surface was decreased by more than 90% compared to control surface.

b) Platelet adhesion

Table 2 summarizes platelet adhesion on the subject coated catheter surfaces and that of the control samples:

Table 2

material	n	Platelet/cm^2 ($x10^5$)
control	4	7.246±0.052
PVP-coated	4	0.055±0.019

Table 2 illustrates the platelet adhesion on both the PVP-coated and control catheters. The hydrophilic coating reduced platelet adhesion by more than 95%. The difference in platelet adhesion was further characterized by Scanning Electron Microscope (SEM) which showed control catheters having numerous platelets attached to the surface thereof while the subject PVP-coated catheters showed little sign of platelet adhesion.

The subject lubricant composition prepared in accordance with the present invention may be applied as a thin surface film, e.g., less than about 4.0 mill but most preferably less than about 2.5 mill in thickness, which upon contact with water or fluid sufficiently reduces the coefficient of friction to aid in the *in vivo* placement of medical devices.

The unexpected significant advantages of the present lubricious coating achieved through the particular composition formulation noted above include decreased wet coefficient of friction, decreased adherence with various surfaces and resistance to wet abrasion.

Medical devices once coated with the subject lubricious coating are to be packaged and sterilized using an appropriate sterilization technique or may be sterilized and then packaged using aseptic technique. Appropriate methods of sterilization and packaging are known to those skilled in the art and include gamma radiation, electronic beam, ethylene oxide, and like methods. Preferably, medical devices coated with the subject lubricious coating are

packaged and then sterilized using gamma radiation by cobalt 60 with 1 to 4 mrads but preferably 2 mrads in two independent exposure cycles for superior results.

Appropriate packaging for the subject coated medical devices includes metallic foil pouches such as aluminum foil pouches, polyethylene film, ethylene vinyl acetate film, polypropylene film, polyvinyl chloride film and like packages known to those skilled in the art, but preferably, a polypropylene tube package or a package having a fibrous layer and a plastic layer with a pocket formed therebetween for storage of the coated medical device.

The method of using the subject coated medical devices comprises removing the device from its packaging, applying moisture to the lubricated surface of the device and placing the device as necessary for a particular medical procedure.

It is seen therefore that the present lubricious coating for medical devices provides an effective wet abrasion resistant, low coefficient of friction coating for medical devices. The lubricious coating, the method of making and using the lubricious coating, the coated medical devices and the method of using the coated medical devices as disclosed and described herein have specific advantages over the heretofore known lubricants for medical devices. The subject lubricious coating resists wet abrasion, adheres to a variety of surfaces, has a decreased coefficient of friction only when wetted and is biocompatible. Hence for these reasons as well as others, some of which hereinabove set forth, it is seen that the present lubricious coating represents a significant advancement in the art which has substantial commercial significance.

While there is shown and described herein certain specific embodiments of the invention, it will be manifest to those skilled in the art that various modifications may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not

limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims.

Claims

WHAT IS CLAIMS IS:

1. A lubricant composition comprising alkylbenzene, polymer, isocyanate-terminated prepolymer and alkylester of a carboxylic acid.

2. The composition of claim 1 wherein said alkylbenzene is selected from the group consisting of toluene, xylene and styrene.

3. The composition of claim 1 wherein said alkylbenzene is toluene.

4. The composition of claim 1 wherein said alkylbenzene is selected from the group consisting of C1-12 alkylbenzenes.

5. The composition of claim 1 wherein said polymer is selected from the group consisting of polyvinylpyrrolidone, polyvinyl alcohol, polyacrylic acid or a derivative thereof, hyaluronic acid or a salt thereof and polyethylene oxide.

6. The composition of claim 1 wherein said polymer is polyvinylpyrrolidone.

7. The composition of claim 1 wherein said alkylester of a carboxylic acid is selected from the group consisting of ethyl lactate, methylbenzoate and propolyacrylate.

8. The composition of claim 1 wherein said alkylester of a carboxylic acid is ethyl lactate.

9. The composition of claim 1 wherein said alkylester of a carboxylic acid is selected from the group consisting of C1-12 alkylesters of carboxylic acids.

10. The composition of claim 1 wherein said isocyanate-terminated prepolymer is selected from the group consisting of polyoxyethylene-based isocyanate prepolymers.

11. The composition of claim 1 wherein said isocyanate-terminated prepolymer is selected from the group consisting of toluene and isophorone diisocyanate-based prepolymers.

12. A lubricant coating for medical devices comprising alkylbenzene, polymer, isocyanate-terminated prepolymer and alkylester of a carboxylic acid.

13. The coating of claim 12 wherein said alkylbenzene is selected from the group consisting of toluene, xylene and styrene.

14. The coating of claim 12 wherein said alkylbenzene is toluene.

15. The coating of claim 12 wherein said alkylbenzene is selected from the group consisting of C1-12 alkylbenzenes.

16. The coating of claim 12 wherein said polymer is selected from the group consisting of polyvinylpyrrolidone, polyvinyl alcohol, polyacrylic acid or a derivative thereof, hyaluronic acid or a salt thereof and polyethylene oxide.

17. The coating of claim 12 wherein said polymer is polyvinylpyrrolidone.

18. The coating of claim 12 wherein said alkylester of a carboxylic acid is selected from the group consisting of ethyl lactate, methylbenzoate and propolyacrylate.

19. The coating of claim 12 wherein said alkylester of a carboxylic acid is ethyl lactate.

20. The coating of claim 12 wherein said alkylester of a carboxylic acid is selected from the group consisting of C1-12 alkylesters of carboxylic acids.

21. The coating of claim 12 wherein said isocyanate-terminated prepolymer is selected from the group consisting of polyoxyethylene-based isocyanate prepolymers.

22. The coating of claim 12 wherein said isocyanate-terminated prepolymer is selected from the group consisting of toluene and isophorone diisocyanate-based prepolymers.

23. A method for producing a lubricant composition comprising blending alkylbenzene, polymer, isocyanate-terminated prepolymer and alkylester of a carboxylic acid until dissolved.

24. The method of claim 23 wherein said alkylbenzene is selected from the group consisting of toluene, xylene and styrene.

25. The method of claim 23 wherein said alkylbenzene is toluene.

26. The method of claim 23 wherein said alkylbenzene is selected from the group consisting of C1-12 alkylbenzenes.

27. The method of claim 23 wherein said polymer is selected from the group consisting of polyvinylpyrrolidone, polyvinyl alcohol, polyacrylic acid or a derivative thereof, hyaluronic acid or a salt thereof and polyethylene oxide.

28. The method of claim 23 wherein said polymer is polyvinylpyrrolidone.

29. The method of claim 23 wherein said alkylester of a carboxylic acid is selected from the group consisting of ethyl lactate, methylbenzoate and propolyacrylate.

30. The method of claim 23 wherein said alkylester of a carboxylic acid is ethyl lactate.

31. The method of claim 23 wherein said alkylester of a carboxylic acid is selected from the group consisting of C1-12 alkylesters of carboxylic acids.

32. The method of claim 23 wherein said isocyanate-terminated prepolymer is selected from the group consisting of polyoxyethylene-based isocyanate prepolymers.

33. The method of claim 23 wherein said isocyanate-terminated prepolymer is selected from the group consisting of toluene and isophorone diisocyanate-based prepolymers.

34. A medical device at least partially coated with a lubricant composition comprising alkylbenzene, polymer, isocyanate-terminated prepolymer and alkylester of a carboxylic acid.

35. The device of claim 34 wherein said alkylbenzene is selected from the group consisting of toluene, xylene and styrene.

36. The device of claim 34 wherein said alkylbenzene is toluene.

37. The device of claim 34 wherein said alkylbenzene is selected from the group consisting of C1-12 alkylbenzenes.

38. The device of claim 34 wherein said polymer is selected from the group consisting of polyvinylpyrrolidone, polyvinyl alcohol, polyacrylic acid or a derivative thereof, hyaluronic acid or a salt thereof and polyethylene oxide.

39. The device of claim 34 wherein said polymer is polyvinylpyrrolidone.

40. The device of claim 34 wherein said alkylester of a carboxylic acid is selected from the group consisting of ethyl lactate, methylbenzoate and propolyacrylate.

41. The device of claim 34 wherein said alkylester of a carboxylic acid is ethyl lactate.

42. The device of claim 34 wherein said alkylester of a carboxylic acid is selected from the group consisting of C1-12 alkylesters of carboxylic acids.

43. The device of claim 34 wherein said isocyanate-terminated prepolymer is selected from the group consisting of polyoxyethylene-based isocyanate prepolymers.

44. The device of claim 34 wherein said isocyanate-terminated prepolymer is selected from the group consisting of toluene and isophorone diisocyanate-based prepolymers.

45. A method of coating at least a portion of a medical device with a lubricious coating comprising:
washing the medical device;
drying the medical device;
applying the lubricious coating;
removing excess lubricious coating; and
baking the medical device.

46. The method of claim 45 wherein said medical device is a catheter.

47. The method of claim 45 wherein said medical device is selected from the group consisting of catheters, arterial venous shunts, gastroenteric feed tubes and endotracheal tubes.

48. The method of claim 45 wherein said lubricious coating comprises alkylbenzene, polymer, isocyanate-terminated prepolymer and alkylester of a carboxylic acid.

49. The method of claim 45 wherein said lubricious coating comprises polymer, isocyanate-terminated prepolymer, alkylester of a carboxylic acid and an alkylbenzene selected from the group consisting of toluene, xylene and styrene.

50. The method of claim 45 wherein said lubricious coating comprises polymer, isocyanate-terminated prepolymer, alkylester of a carboxylic acid and toluene.

51. The method of claim 45 wherein said lubricious coating comprises polymer, isocyanate-terminated prepolymer, alkylester of a carboxylic acid and an alkylbenzene selected from the group consisting of C1-12 alkylbenzenes.

52. The method of claim 45 wherein said lubricious coating comprises an isocyanate-terminated prepolymer, an alkylester of a carboxylic acid, an alkylbenzene and a polymer selected from the group consisting of polyvinylpyrrolidone, polyvinyl alcohol, polyacrylic acid or a derivative thereof, hyaluronic acid or a salt thereof and polyethylene oxide.

53. The method of claim 45 wherein said lubricious coating comprises an isocyanate-terminated prepolymer, an alkylester of a carboxylic acid, an alkylbenzene and polyvinylpyrrolidone.

54. The method of claim 45 wherein said lubricious coating comprises an isocyanate-terminated prepolymer, an alkylbenzene, a polymer and an alkylester of a carboxylic acid selected from the group consisting of ethyl lactate, methylbenzoate and propolyacrylate.

55. The method of claim 45 wherein said lubricious coating comprises an isocyanate-terminated prepolymer, an alkylbenzene, a polymer and ethyl lactate.

56. The method of claim 45 wherein said lubricious coating comprises an isocyanate-terminated prepolymer, an alkylbenzene, a polymer and an alkylester of a carboxylic acid selected from the group consisting of C1-12 alkylesters of carboxylic acids.

57. The method of claim 45 wherein said lubricious coating comprises alkylbenzene, polymer, an alkylester of a carboxylic acid and an isocyanate-terminated prepolymer selected from the group consisting of polyoxyethylene-based isocyanate prepolymers.

58. The method of claim 45 wherein said lubricious coating comprises alkylbenzene, polymer, an alkylester of a carboxylic acid and an isocyanate-terminated prepolymer selected from the group consisting of toluene and isophorone diisocyanate-based prepolymers.

59. The method of claim 45 wherein said washing comprises dipping the medical device in isopropanol.

60. The method of claim 45 wherein said drying comprises exposing the medical device to forced air of 50 to 90 degrees Celsius.

61. The method of claim 45 wherein said drying comprises exposing the medical device to forced air of 80 degrees Celsius.

62. The method of claim 45 wherein said applying of the lubricious coating comprises dipping a warm medical device into the coating for about 2 to 15 seconds.

63. The method of claim 45 wherein said removing of excess coating comprises drying the medical device at room temperature.

64. The method of claim 45 wherein said removing of excess coating comprises removal with absorbent towels.

65. A method of coating a medical device with the composition of claim 1 or 68 comprising cleaning and drying the medical device, dip coating the medical device in said lubricant composition, air drying the device and baking the device.

66. A method of preparing a lubricant composition comprising blending polyvinylpyrrolidone, ethyl lactate, toluene and isocyanate-terminated prepolymer until dissolved.

67. A method of preparing a lubricant composition comprising blending 1 to 4 weight percent polyvinylpyrrolidone, 15 to 25 weight percent ethyl lactate, 60 to 80 weight percent toluene and 0.5 to 3 weight percent isocyanate-terminated prepolymer.

68. A lubricant composition comprising 1 to 4 weight percent polyvinylpyrrolidone, 15 to 25 weight percent ethyl lactate, 60 to 80 weight percent toluene and 0.5 to 3 weight percent isocyanate-terminated prepolymer.

69. A method of using a medical device having at least a portion of the surface thereof coated with the lubricant composition of claim 1 or 68 comprising removing the device from packaging, applying moisture to the coated surface of the device and placing the device in position as required for a particular medical procedure.

70. A method of using the lubricant composition of claim 1 or 68 comprising dip coating a medical device in said lubricant composition, drying said lubricant composition on said device and baking said device coated with said lubricant composition whereby said lubricant composition provides a reduced coefficient of friction of the device when wetted.